IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO: ETHICON WAVE 5 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.

Dr. Elliott has been the target of multiple *Daubert* motions over the past three years. In that time, his opinions have largely remained the same. In fact, his reports in these Wave cases have not materially changed. In Wave 1, Ethicon challenged all of his opinions and the Court ruled on those challenges. (Doc. No. 2666). In Wave 2 Ethicon adopted its Wave 1 challenges and the Court adopted its earlier rulings. (Doc. No. 3528). For Wave 3, Ethicon decided it was unhappy with the Court's earlier rulings and it levied another scattershot attack on most of Dr. Elliott's opinions. The Court rejected Ethicon's attempt to get a second bite at the apple and adopted its earlier Order reserving for trial any new or newly nuanced attacks. (Doc. No. 4152). Now, Ethicon has decided it is still unhappy with the Court's rulings and is trying to get a third bite at the apple. Notably, Ethicon does not argue that Dr. Elliott materially modified his report or his opinions -- he did not. Ethicon does not argue there is some new testimony undermining Dr. Elliott's opinions – there is not. Ethicon just wants another bite. The Court should summarily deny Ethicon's Motion seeking to revisit issues the parties have fully briefed and this Court has already decided. The Court should adopt its earlier rulings in Wave 1 and Wave 3 and move these cases toward trial.

BACKGROUND

The Court is well acquainted with Dr. Elliott's *bona fides*. Dr. Daniel S. Elliott is an associate professor of urology in the section of Female Urology and Reconstructive Surgery at the Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. He has treated hundreds of patients with mesh-related complications. For over 15 years, he has specialized in treating urinary incontinence in women. He has delivered numerous lectures on treatment options for stress urinary incontinence (SUI) in women, including the limitations of each. He is an editor or reviewer for 15 urologic and gynecologic journals and has reviewed all readily available medical literature on SUI treatment options. He has also reviewed an extensive number of internal Ethicon documents and depositions of its personnel in developing his opinions in these cases.

Dr. Elliott has extensive experience implanting both naturally made and synthetic slings to treat SUI, including polypropylene slings. In fact, synthetic slings were his primary treatment for SUI prior to August, 2013. He implanted several hundred synthetic slings during that time period.

ARGUMENT

I. Ethicon Is Simply Regurgitating Its Previous Attacks on Dr. Elliott (as it did in Wave 3) and the Court Should Deny Ethicon's Motion and Adopt Its Earlier Rulings.

This Court has expressly informed the parties that it does not desire *Daubert* do-overs and that such motions waste the Court's and parties' time. In its Wave 3 *Daubert* Order concerning Dr. Elliott, the Court simply adopted its prior Wave 1 ruling noting "the court will refrain from engaging in the extremely inefficient practice of continuously reexamining qualifications, reliability, and relevance of dozens of experts and their numerous opinions." (Doc. 4152 at 2).

Here, Ethicon's Wave 5 *Daubert* Motion is essentially a wholesale regurgitation of its Wave 1 and Wave 3 motions. In fact, large portions of the Motion are a word-for-word recitation

of Ethicon's Wave 1 and Wave 3 motions. In instances where the present Motion differs from earlier briefs, the "new" issues raised are either wholly irrelevant or are being raised for the first time after years of litigation.

Notably, Ethicon does not allege that Dr. Elliott has materially changed any of his opinions – he has not – nor that there is any new testimony from Dr. Elliott undermining this Court's previous rulings – there is not. Instead, Ethicon largely seeks to have the Court reconsider its earlier rulings with which it disagrees or to attack whole new portions of Dr. Elliott's opinions despite the fact that these opinions have not materially changed for years.

On August 26, 2016, this Court issued its Wave 1 Memorandum Opinion and Order on *Daubert* Motion re: Daniel Elliott, M.D. In this Order, the Court thoroughly assessed Dr. Elliott's qualifications and the reliability and relevance of the opinions he sought to offer. The Court determined that Dr. Elliott could offer some opinions, could not offer others, and, that certain decisions were best reserved for determination at the time of trial. (Doc. No. 2666).

For Wave 2 cases, the parties adopted their Wave 1 briefing and the Court simply adopted its Wave 1 Order. (Dkt. 3528). This reflected the Court's desired approach when dealing with the same expert who had issued a similar report in earlier Waves.

In Wave 3, apparently becoming dissatisfied with the Court's Wave 1 ruling, Ethicon filed a new *Daubert* challenge against Dr. Elliott. On July 20, 2017, this Court issued an Order regarding Dr. Elliott's opinions in Wave 3. (Doc. No. 4152). The Court noted that "the expert opinions proffered [by Dr. Elliott] in Wave 1 are in almost every respect identical to those proffered here [in Wave 3]." *Id.* Recognizing that "these refreshed *Daubert* challenges are different from previous arguments by only the very slightest of degrees," the Court adopted its earlier Wave 1 Order on all previously determined issues and reserved ruling on any new issues

holding that "the trial judge may easily resolve these issues at trial without the need for further briefing or evidentiary hearing." *Id.* at 2.

Now, Ethicon seeks once again to reopen issues the parties have fully briefed and this Court has thoroughly addressed in both Waves 1 and 3 or which it failed to raise in its Wave 1-4 briefing. In essence, Ethicon seeks a third bite at the apple. Ethicon even admits that its Wave 5 Motion largely mirrors their earlier motions. *Memorandum in Support of Defendants' Motion to Exclude Certain General Opinions of Daniel Elliott, M.D.* at 1 (Doc. No. 4367) ("Ethicon's brief in this wave of cases is very similar to its brief submitted for the Wave 3 cases….") (hereinafter, "Motion"). Ethicon concedes that Dr. Elliott has not issued a materially new report or that he has any new opinions. Instead, Ethicon admits it wants the Court to revisit earlier rulings or consider Ethicon's new arguments that Ethicon failed to raise in the past. *Motion* at 1 ("Ethicon presents the following arguments that have not previously been argued and/or that have been supplemented with additional authorities…."). Ethicon's attempt to relitigate Dr. Elliott's opinions is wholly improper and an inefficient use of judicial resources. Accordingly, the Court should summarily deny Ethicon's Motion and adopt its earlier rulings.[1] Out of an abundance of caution, Plaintiffs address Ethicon's individual claims.

II. Dr. Elliott is Qualified to Testify Regarding Product Warnings.

In every one of his experts reports from Wave 1 through *Mullins* and this Wave 5 report, Dr. Elliott has consistently opined about the risks of implanting mesh, whether or not those risks

[1] Ethicon's Motion is effectively an improper motion to reconsider this Court's earlier rulings. As this Court noted in *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 649 (S.D.W. Va. 2013), "it is improper to file a motion for reconsideration simply to ask the Court to rethink what the Court had already thought through—rightly or wrongly." *Id.* (quoting *Mt. Hawley Ins. Co. v. Felman Production, Inc.*, No. 3:09–cv–00481, 2010 WL 1404107, at *2 (S.D.W.Va. Mar. 30, 2010)).

appeared in the various instructions for use ("IFUs"), and whether the undisclosed risks should have appeared in the IFUs. In fact, the language he used in all of those reports is essentially identical and Ethicon does not identify any new opinions. Now, for the first time, Ethicon insists that Dr. Elliott's testimony should be "confined" to exclude testimony about "what information should or should not be included in an IFU." *Motion* at 3.

To be clear, Ethicon had the opportunity to raise this issue in earlier briefing – yet, it has never done so. In fact, the terms "IFU", "instructions for use" or "warning" do not appear anywhere in Ethicon's Wave 1 or Wave 3 *Daubert* motions against Dr. Elliott. Especially considering the magnitude and complexity of this MDL, the Court should not permit Ethicon to serially relitigate Dr. Elliot's opinions after multiple briefs have been completed and the Court has issued multiple opinions. Ethicon waived its right to challenge Dr. Elliott's IFU/Warnings opinions. On this basis alone, the Motion should be denied.

Assuming the Court wishes to assess the substance of Ethicon's reconsideration Motion and new arguments, it is evident that Dr. Elliott is qualified to testify regarding warnings and the IFU. In fact, Defendants admit that Dr. Elliott is qualified to testify regarding the risks of implanting mesh and "whether specific risks appeared in the IFUs." *See Motion* at 3 (quoting this Court: "[A]n expert who is an obstetrician and gynecologist may testify about the specific risk of implanting mesh and whether those risks appeared in the relevant IFU…."). This is also consistent with this Court's ruling concerning Dr. Elliott in the *Cook MDL* where this Court held that Dr. Elliott was indeed qualified to identify the risks associated with the use of a mesh product and "explain[] that the IFU and defendant's product literature fails to disclose these risks." This Court held as follows:

> Cook contends Dr. Elliott is not qualified to opine on product warnings or labels….
> "Dr. Elliott's report identifies particular risks with SIS biomaterials and explains

> that the IFU and defendant's product literature fails to disclose these risks." (Id.). I agree with the plaintiff that a urologist like Dr. Elliott is qualified to make this comparison. *See Wise v. C.R. Bard, Inc.*, No. 2:12–cv–01378, 2015 WL 521202, at *9–10 (S.D.W.Va. Feb.7, 2015) (finding a urogynecologist qualified to opine on product labeling based on his knowledge and clinical experience); *see also Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 719 (S.D.W.Va.2014) (finding a urologist qualified to opine on the risks of implanting a product and whether those risks were adequately expressed on the product's IFU).

Watkins v. Cook Inc., No. 2:13-CV-20370, 2015 WL 1395773, at *10 (S.D.W. Va. Mar. 25, 2015).

Hence, the only relief Ethicon seeks is to prevent Dr. Elliott from opining on "whether other risks should or should not be included in an IFU." *Motion* at 3 & 17 (internal quotations omitted). As noted above, Dr. Elliott's reports have consistently contained opinions on these very issues and have never been challenged before. For example, in his TVT report, Dr. Elliott opines as follows:

> The IFU's Adverse Reactions section says that over correcting, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction, yet the surgeon has been previously provided with five conflicting and confusing instructions to place the tape with (1) minimal tension, (2) tension free, (3) loosely, (4) without tension, and (5) to adjust the tail of the TVT mesh until leakage is limited. This leaves the physician with no clear, articulable standard on how to avoid the serious adverse reaction of urinary retention or urinary obstruction.

(attached as Ex. C to Ethicon's Motion (Doc. No. 4364-3) at 31-32). Similarly, in his Prolift report, Dr. Elliott discusses the adequacy of the IFU as it relates to the surgical perspective and the practical impact it has on the implanting surgeon. He opines as follows:

> Hydrodissection is a surgical step used to create a space between the vagina and the rectum and/or bladder. The purpose of this step is to identify and surgically enter the rectovaginal/vesicovaginal space more easily and to reduce the risk of injury to the adjacent rectum and/or bladder. This step would seem even more important given the differences between vaginal dissections in Prolift procedures versus traditional procedures. However, the Prolift IFU makes no mention of vaginal wall hydrodissection.

(attached as Ex. F to Ethicon's Motion (Doc. No. 4364-6) at 43). Ethicon has never challenged these opinions as beyond Dr. Elliott's qualifications. There is a reason for that – he is qualified to give them.

Ethicon argues that Dr. Elliott's "curriculum vitae does not identify any additional expertise to render an opinion about the adequacy of Ethicon's IFU…." However, as reflected in Dr. Elliott's resume, he has extensive experience in the testing and development of medical devices. Dr. Elliott work on the initial animal studies and the clinical design for a male incontinence device. He also developed a rectus fascial harvester medical device for which he owns the patent. *See Dr. Elliott's Curriculum Vitae* at 22 (attached as Ex. B to Ethicon's Motion (Doc. No. 4364-2). Dr. Elliott testified concerning his experience in the development of these devices:

> Well…if you look at my CV, I was involved in transurethral enzymatic ablation of the prostate, which I worked with a researcher and the founder of the company and working with the FDA as far as getting it approved, that's when I was a resident. I worked with the design of a new artificially designed urinary sphincter for males …, so we were working on the standards with the companies, and then my own patent.

See Ex. 1, *Hammons Depo.* at 256:14-22. Accordingly, Dr. Elliott has direct experience with product design and development and the related FDA approval processes.

Moreover, Dr. Elliott has testified that he has extensive experience teaching residents about the intricacies of an IFU. In *Hammons,* he testified as follows:

> Q. As part of your training and teaching of residents, do you have occasion to teach with regard to IFUs, the instructions for use for medical devices?
> A. It would be on a daily basis with residents, especially new residents who are coming on my service, we go over the IFUs, if we're using a medical device, and then if there's a new product that comes out, we'll review those.
> Q. When you teach residents about the IFU, what are the types of things you focus on when you're actually teaching day-to-day?
> A. Well, we go over everything. It depends upon if it's a new resident or not. Let's take a new resident, typical one, it's every six weeks I have a new

> resident on my service. We sit down, we go over the IFU, we go over the procedure, how it's described and then the various different warnings or potential complications.
>
> Q. As part of that process, have you learned what it is that you're looking for in an IFU and what needs to be taught to physicians to look for?
>
> A. Oh, absolutely…

Ex. 1, *Hammons Depo*. at 10:12-11:9. This experience clearly permits Dr. Elliott to opine about what should or should not have been in an IFU. Finally, in *Bellew v. Ethicon, Inc.,* No. 13-cv-22473, Mem. Op. & Order, Dkt. No. 265, (Nov. 20, 2014), this Court held that Dr. Elliot should be permitted to testify regarding "whether Ethicon provided **sufficient guidance** to surgeons through the Prolift [IFU], the Surgical Guide, and any training programs offered." *Id.* at 24 (emphasis added).

Accordingly, the Court should refuse to entertain Ethicon's late attack on Dr. Elliott's warning opinions. Moreover, even if the Court does entertain Ethicon's new arguments, the Motion should still be denied. In addition to his training and experience as a Urogynecologist, Dr. Elliott has unique expertise in medical device development and training other physicians regarding IFUs which permits him to testify on whether certain warnings should or should not have been included in the IFUs. Finally, in the context of the Prolift litigation, this Court has already determined that Dr. Elliot was qualified to do so. Ethicon's Motion should be denied.

III. This Court Has Already Ruled That, Whether Dr. Elliott May Testify About Non-Synthetic Mesh Procedures Should Be Determined on A Case-By-Case Basis.

Defendants seek a blanket ruling preventing Dr. Elliott from testifying about non-synthetic mesh products and procedures. Defendants argue such testimony is not relevant for purposes of a design defect claim and that, even if relevant, Dr. Elliott's opinions are unreliable. Defendants' argument concerning Dr. Elliott's testimony is yet another rehash of their Wave 1 *and* Wave 3 motions. Apparently, Ethicon is not happy with the Court's previous rulings on this issue and, as

they admit in their motion, they believe "that this should be revisited." *Motion* at 4. Absent extenuating circumstances, which do not exist here, the Court should not countenance Ethicon's attempt at a belated motion for reconsideration. The Court has previously rejected these precise arguments and should do so again by adopting its Wave 1 and Wave 3 orders on these issues.

A. The Court should not issue a categorical exclusion of testimony about non-mesh alternatives when such evidence is relevant to numerous claims, including failure to warn, negligence,, impeachment, and potentially design defect.

Ethicon argues that evidence concerning non-mesh alternative treatments is irrelevant. However, the Court previously rejected Ethicon's argument during Wave 1, and the Court should not now backtrack from its sound conclusion.

Ethicon asks that this Court hold that Dr. Elliott's opinions regarding the safety of non-mesh procedures should be universally declared as irrelevant to all trials in all cases in Wave 5—regardless of the applicable state law and regardless of the evidence, claims, and arguments in a particular case. When faced with this issue previously, the Court wrote:

> *First*, Ethicon argues that Dr. Elliott should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Expert testimony on this subject, Ethicon claims, is not relevant. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I **RESERVE** ruling until trial.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 8. This was then, and still is, the correct conclusion to reach when assessing the relevance of evidence. Under Rule 401, the standard for relevance is not high. To be relevant, evidence must have "any tendency to make a fact more or less probable than it would be without the evidence," and the fact must be "of consequence in determining the action." Fed. R. Evid. 401(a)-(b). Relevance is more appropriately addressed through motions in limine by the trial court as an evidentiary issue depending on the facts of the specific case and the applicable law.

In *Mullins*, this Court applied West Virginia law and held that "evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." *Mullins v. Johnson & Johnson*, No. 2:12-CV-02952, 2017 WL 711766, at *2 (S.D. W. Va. Feb. 23, 2017). However, *Mullins* should not be read so broadly as to categorically exclude this evidence from all cases. For example, not all states require evidence of a safer alternative design or that such evidence be from another similar product. Moreover, at the time of the Court's ruling, *Mullins* had been limited to solely defective design claims. Clearly, such evidence may be relevant when assessing failure to warn claims, negligence claims, warranty claims or as impeachment evidence against Ethicon's contentions that its products are the "gold standard." A recent ruling from the Northern District of Illinois provides an important example of why the Court should not issue a blanket ruling prohibiting such testimony, but should instead adopt its Wave 1 ruling that this should be decided on a case-by-case basis.

In *Herrera-Nevarez v. Ethicon, Inc.*, No. 12-C-2404, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017), Ethicon requested that the court adopt the *Mullins'* ruling to exclude Dr. Elliott's testimony regarding non-mesh alternate procedures for treatment of SUI. In analyzing Ethicon's Motion, the Court noted that, under Illinois law and the particular facts of the case, the decision in *Mullins* could not simply be applied in a blanket fashion to bar all such testimony. While the court noted that the evidence may not come in to demonstrate the availability of substitute products, the court noted that, under Illinois' risk/utility test, such testimony was clearly relevant and admissible. In addition, the court held that the testimony would also be relevant to impeach Ethicon's claims that its products were the "gold standard". The court held as follows:

> Under Illinois product liability law, a plaintiff may attempt to prove that the design of a product is unreasonably dangerous using the "risk-utility" test. Factors considered when applying this test include:

> (1) the utility of the product to the user and the public;
> …
> (3) the availability of a substitute product that would meet the same need, more safely;
>
> Defendants argue that other surgical procedures are not "substitute products" whose utility and safety is relevant under factor 3, and the Court agrees. **But the availability of other safe and effective procedures to treat the same condition is relevant and admissible, as plaintiffs contend, to show the utility of the defendants' product (factor 1)—a point not addressed in the other cases upon which defendants rely. The Court also notes that this evidence is admissible to rebut defendants' contention that the TVT-O and similar products are the "gold standard" for treating SUI**.

Id. at *7 (emphasis added).

In its *Motion*, Ethicon relies upon a different Illinois remand case addressing the opinions of Dr. Shull, not Dr. Elliott. *Motion* at 5 (citing *Walker v. Ethicon, Inc.*, No. 12-CV-1801, 2017 WL 2992301, at *3 (N.D. Ill. June 22, 2017)). In *Walker*, the court held that Dr. Shull would not be permitted to testify regarding non-synthetic mesh alternatives. The different outcomes in these two cases only further confirms this Court's original ruling -- the relevance of this evidence should be determined on a case-by-case basis by the court examining the specific facts and law to be applied in a given case. Ethicon's Motion should be denied and the Court should adopt its original ruling reserving this decision for trial.

B. Dr. Elliott's opinions regarding non-synthetic mesh alternatives are based on a detailed analysis backed by reliable evidence.

Ethicon again repeats, essentially word for word, the same arguments that it leveled against Dr. Elliott in Waves 1 and 3. Ethicon does not cite to any new opinions or testimony on the subject – instead it simply seeks reconsideration of this Court's earlier ruling without meeting the standards for reconsideration outlined above. For this reason alone, the Court should deny Ethicon's repetitive, wasteful *Motion*.

In its Wave 1 Order, the Court appropriately reserved ruling on this issue until the time of trial when Dr. Elliott's clinical experience could be appropriately tested. The Court held as follows:

> Ethicon objects to the reliability of Dr. Elliott's expert testimony about whether alternative procedures are safer than Ethicon's mesh products. In my view, the reliability of this expert testimony is heavily dependent on Dr. Elliott's clinical experiences. In the abstract, experience-on its own or accompanies by little else-is a reliable basis for expert testimony. But the reliability inquiry must probe into the relationship between the experience and the expert testimony…. Here, the court does not have enough information to judge the reliability or relevance of D.r. Elliott's particular experience.
>
> In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony based primarily on an expert's clinical experiences. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 8-9. The Court then adopted this ruling in its Wave 3 Order. (Doc. No. 4152) at 1.

There has been no new evidence, no further testimony from Dr. Elliott, and no trial. Hence, Ethicon's attempted redo on this issue should be denied. The Court should, as it did in Wave 3, adopt its earlier ruling reserving this issue for trial.[2]

IV. Dr. Elliott's Testimony Properly Explains the Superiority of Other Synthetic Products, Notwithstanding His Claim That Synthetic Products Overall Are Inferior.

In its Motion, Defendants state that Dr. Elliott should not be permitted to suggest that other mesh products, such as TVT-R and TVT-O, offer a safer alternative to the TVT-S. Motion at 11. Admittedly, Dr. Elliott is not an advocate for any synthetic mesh, finding all of them to pose inherent dangers. But that general opinion does not detract from the reliability of his testimony that mesh products configured differently than the TVT-S are safer. *See Nease v. Ford Motor Co.*

[2] To the extent necessary, Plaintiffs incorporate their arguments on this issue as set forth in their Wave 3 Response brief. (Doc. No. 2952, Section II).

Civ. Act. No. 3:13-29840, 2015 WL 4508691, at *5 (S.D.W. Va. July 24, 2015) (Chambers, J.) ("If a product can be made safer and the danger may be reduced by an alternative design at no substantial increase in price, then the manufacturer has a duty to adopt such a design."). Indeed, an alternative design must only be a "safer alternative." "It need not eliminate all potential risks to be safer." *Thomas v. CMI Terex Corp.*, Civ. No. 07-3597 (JBS/KMW), 2009 WL 3068242, at *16 n. 15 (D.N.J. Sept. 21, 2009). The alternative must "not be as unsafe" as the product at issue, not "safe" in the abstract. *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 573 (E.D. Pa. 2011).

When faced with a similar argument in the Wave 1 briefing this Court specifically held that Dr. Elliot was qualified to testify regarding the comparative safety of other mesh products. The Court held as follows:

> Considering Dr. Elliott's medical education and background and his vast experience treating patients with mesh complications, he is qualified to testify about whether one mesh product is safer than another. Ethicon's Motion is **DENIED** on this point.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 9. This is consistent with a decision in a recently remanded case.

In *Herrera-Nevarez*, the court held that Dr. Elliott's opinions were admissible despite the fact that "he does not believe that any such devices are safe…." There, the court held as follows:

> The Court also overrules defendants' contention that Dr. Elliott should not be permitted to testify that other synthetic mesh devices are safer than the TVT-O. The fact that he evidently does not believe that any such devices are safe does not preclude him from ranking them on a comparative basis. This affects only the weight to be given to Dr. Elliott's testimony on this point, not its admissibility. Defendants are, of course, free to cross-examine Dr. Elliott regarding his views of mesh devices generally and regarding any inconsistent testimony or statements he has given.

Herrera-Nevarez v. Ethicon, Inc., No. 12 C 2404, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017). Ethicon's Motion should be denied.

V. Dr. Elliott's Opinions Concerning Lighter Weight/Larger Pore Size Mesh Are Reliable.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section III.C of Doc. No. 2952.

VI. Dr. Elliott's Opinions Concerning Mechanical Cut vs. Laser Cut Are Reliable.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section IV of Doc. No. 2952.

VII. This Court Has Already Reserved Ruling on Whether or Not Dr. Elliott May Offer Opinions Regarding Testing, Adverse Events and Training.

Defendants claim Dr. Elliott should not be permitted to testify regarding Ethicon's failure to test its devices, adverse event reporting and training. Motion at 13-17. Again, Defendants have made these precise arguments since Wave 1. Importantly, in Wave 1, this Court correctly reserved ruling on these issues "because the scope of relevant testimony may vary according to differences in state products liability law" and the facts of the particular case. This Court concluded as follows:

> I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 13. This Court later adopted this holding in its Wave 3 Order noting, "the Court will refrain from engaging in the extremely inefficient practice of continuously reexamining the qualifications, reliability, and relevance of dozens of experts and their numerous opinions." *Wave 3 Memorandum Opinion and Order* (Doc. No. 4152) at 2. The Court should again adopt this reasoning and deny Ethicon's *Motion*.

As noted, Ethicon's briefing on this issue is identical to its briefing in Wave 1 and Wave 3. The only change Ethicon identifies since its earlier briefing is a trial court decision in Illinois regarding an entirely different expert. *See Motion* at 15 (discussing *Walker v. Ethicon Inc.*, 2017 WL 2992301 (N.D. Ill. June 22, 2017) (addressing Dr. Shull)). However, *Walker* only adds

additional support to the Court's decision to allow the appropriate trial court to apply the laws and facts of the case before it when determining the relevance of this testimony. *Walker* demonstrates that the Court's approach to reserve ruling actually works.

As Ethicon's briefing on this, with the exception of its citation to *Walker*, mirrors its earlier briefing, Plaintiffs will not burden the Court with a re-recitation of its opposition to these points. Instead, Plaintiffs, acknowledging the Court's admonishments about inefficiencies, adopt their Response to these issues from their Wave 3 brief. *See* Section V of Doc. No. 2952.

VIII. Dr. Elliott's Testimony Regarding Problems With the TVT Mesh Are Reliable.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section VI of Doc. No. 2952.

IX. Dr. Elliott Will Not Offer Opinions Related to the TVT-Exact.

Ethicon argues that Dr. Elliott, never having issued a TVT-Exact report, should not be permitted to provide opinions regarding the TVT-Exact. Plaintiffs agree. Dr. Elliott will not offer any opinions regarding the TVT-Exact device.

X. This Court Has Already Held That Dr. Elliott's "Marketing" Opinions Are Proper.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section VII of Doc. No. 2952.

CONCLUSION

To the extent Ethicon refused to adopt its earlier arguments and chose instead to make new arguments or tweak old arguments, the Court should decline to engage in Ethicon's patent attempt at reconsideration. As noted, Dr. Elliott's reports have not materially changed and Ethicon fails to identify any new opinions or testimony. The Court should reject Ethicon's attempt at a third bite at the apple and simply adopt its earlier Wave 3 rulings.

Date: August 29, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2017 I electronically filed the foregoing **PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.** with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Jenelle Cox
Jenelle Cox